

REMARKS

The Office Action

Claims 1-3, 6, and 7 are pending. Claims 1 and 3 stand rejected under 35 U.S.C. § 102(e) for anticipation by Boismenu et al. (U.S. Patent Application Publication No. 2005/0002922, hereafter “Boismenu”). Claims 1-3 stand rejected under 35 U.S.C. § 103 for obviousness over Boismenu, and claims 1-3, 6, and 7 are rejected for obviousness over Boismenu in view of Renshaw (U.S. Patent Application Publication No. 2002/0019364). These rejections are discussed in detail below.

Rejections under 35 U.S.C. § 102

Claims 1 and 3 are rejected under 35 U.S.C. § 102(e) as being anticipated by Boismenu. Applicants traverse the rejection and provide the enclosed Declaration under 37 C.F.R. § 1.131 of prior invention and corresponding Exhibit.

M.P.E.P. § 2136.05 states that “a 35 U.S.C. 102(e) rejection can be overcome by antedating the filing date...of the reference by submitting an affidavit or declaration under 37 CFR 1.131,” but the rejection must not rely on a “U.S. patent application publication of a *pending* or patented application to another or others which claims the same patentable invention as defined in [37 C.F.R.] § 41.203(a)” (37 C.F.R. § 1.131(a)(1), emphasis added).¹ The affidavit or declaration must state facts to establish prior invention, and these facts must show:

- (A) (actual) reduction to practice of the invention prior to the effective date of the reference; or
- (B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or
- (C) *conception* of the invention prior to the effective date of the reference *coupled with due diligence from prior to the reference date to the filing date* of the application (constructive reduction to practice). (M.P.E.P. § 715.07, Part III, emphasis added)

¹ U.S. Patent Application No. 10/800,344 for Boismenu is no longer pending and has been abandoned as of October 29, 2007 (mail date of the Notice of Abandonment). Thus, the exception recited in 37 C.F.R. § 1.131(a)(1) does not apply.

Conception requires “contemporaneous recognition and appreciation of the invention” (§ M.P.E.P. 2138.04, Part III). Diligence requires “affirmative acts or acceptable excuses,” and work relied upon to establish diligence “must be directly related to the reduction of practice of the invention” (§ M.P.E.P. 2138.06). The enclosed Declaration and Exhibit meets these standards to establish invention prior to the effective date of Boismenu.

The Declaration provides evidence of prior invention by Drs. Yurgelun-Todd and Renshaw, the inventors of the subject matter described and claimed in the present application. Dates and contact information have been redacted from the Exhibit, and relevant timeframes are established within the body of the declaration, under M.P.E.P. § 715.07, Part II.

First, the Declaration establishes conception of the invention prior to March 13, 2003, the effective date of Boismenu. As stated by the inventors in the Declaration (§¶2-3), “[t]he enclosed Exhibit is a copy of an invention disclosure, which shows that we had conceived the invention of the relevant claims prior to March 13, 2003. In particular, these pages show conception of the use of secretin for the treatment of bipolar disorder and other psychiatric disorders. The invention was conceived in the U.S. As is stated in the Exhibit, we believed that the effects of secretin may be mediated, in part, by its effects on the amygdala. We further employed fMRI in the study of adolescents with bipolar disorder and observed abnormalities in the amygdala of these subjects.”

Second, the Declaration establishes diligence from prior to the effective date of Boismenu up to the effective filing date of the above-captioned application (i.e., the filing date of the provisional application relied on for priority). As stated by the inventors in the Declaration (§¶4), “[w]e diligently worked to reduce the invention to practice from just prior to March 13, 2003 to May 13, 2003, the filing date of the provisional application from which this application claims priority.” The inventors carried out various tasks in the U.S., including their work on an NIMH grant proposal to obtain federal funding to conduct studies of facial affect in patients with bipolar disorder during February – March, 2003 and their development of a protocol to study masked vs. unmasked facial affect

using fMRI between February and April, 2003. The inventors state that “[t]hese experiments are relevant as bipolar subjects demonstrate altered amygdalar activation during facial affect tasks, and secretin modifies amygdalar activation during facial affect task.” Other tasks carried out by the inventors in the U.S. include working to demonstrate prefrontal cortex modulation of amygdalar activation in bipolar disorder from February to May, 2003; developing methods to increase the ability of fMRI to determine the effects of secretin on the central nervous system from March 2003 through May 13, 2003; and developing a protocol to assess the effects of secretin on brain activation in patients with schizophrenia from April to May, 2003. The inventors state that “[t]hese activities are relevant to the invention because we believe that secretin produces a therapeutic effect at least in part through effects on the amygdala, and these studies sought to confirm a connection between bipolar disorder and schizophrenia and abnormalities of the amygdala.” Thus, the Declaration provides prior conception coupled with diligence from just prior to the effective date of Boismenu to the effective filing date of the above-captioned application, and Boismenu is not prior art against the pending claims. For this reason, this rejection may now be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-3 stand rejected under 35 U.S.C. § 103 for obviousness over Boismenu, and claims 1-3, 6, and 7 are rejected for obviousness over Boismenu in view of Renshaw (U.S. Patent Pub. No. 2002/0019364). These rejections primarily rely on Boismenu, and Boismenu is not prior art, as discussed above. Accordingly, these rejections should be withdrawn.

Information Disclosure Statement

Applicants submit herewith PTO Form-1449 including the previously submitted reference “Repligen Corporation. “SecreFlo™ (Secretin) for Injection.” (2002).” This Form-1449 provides the number of pages of this reference in parentheses, and a copy of this reference is being provided again. Applicants request that the Examiner consider all

the references on this Form-1449, including this previously submitted reference, and return an initialed Form-1449 with the next Action.

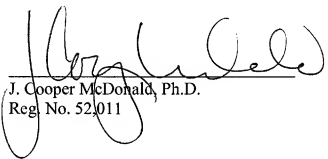
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

If there are any additional charges or any credits required to maintain pendency, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 11/24/10



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